UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,937	03/19/2004	Bela Anand-Aptc	CCF-6494NP	8141

26294 7590 02/08/2006

TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.
1300 EAST NINTH STREET, SUITE 1700
CLEVEVLAND, OH 44114

EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,937	ANAND-APTE, BELA	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 13, 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to drawn to a purified polypeptide comprising a portion of the C-terminal domain of TIMP-3, classified in class 530, subclass 300.

II. Claims 14-21, drawn to drawn to a method of inhibiting VEGF binding to the VEGF Receptor 2 (VEGFR2), classified in class 514, subclass 12.

III. Claims 22-24 (the first claim 24), drawn to a method of targeting or delivering a diagnostic agent to cells expressing VEGFR2, classified in class 424, subclass 9.1.

IV. Claim 22-24 (the first claim 24), drawn to a method of targeting or delivering a therapeutic agent to cells expressing VEGFR2, classified in class 514, subclass 12.

V. Claims claim(s) 24 (the second claim 24) - 27, drawn to a method of inhibiting VEGF-induced endothelial cell proliferation or migration, classified in class 435, subclass 375.

VI. Claim 28, drawn to drawn to a vector comprising a nucleotide sequence encoding TIMP-3 or a variant thereof, classified in class 435, subclass 320.1.

VII. Claims 29-30, drawn to a method of treating angiogenic disease and a method of delivering a therapeutic agent to angiogenic blood vessels associated with disease, classified in class 514, subclass 12.

VIII. Claim 30, drawn to drawn to a method of method of delivering a diagnostic agent to angiogenic blood vessels associated with disease, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons.

Inventions I and VI are related as a portion of a protein and a vector containing a nucleic acid sequence that encodes the protein. But, inventions are separate and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid molecule has utility for the recombinant production of the protein in a host cell. But, these are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source or by synthetic means. Further, the nucleic acid molecule can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

Inventions I and the set of II-V, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in each of the methods of Groups II-V, VII and VIII, e.g., the protein fragment of Group I can be used to deliver a diagnostic agent (Group III), to deliver a therapeutic agent (Group IV), to inhibit endothelial cell proliferation (Group V) or to treat angiogenic disease (Group VII). Therefore, these inventions are patentably distinct.

Inventions VI and the set of II-V, VII and VIII are related in that the vector of Group VI contains a nucleic acid sequence that encodes the protein of which the protein of Group I is a fragment, and the protein fragment of Group I can be used in each of these methods. But, this vector is not required for and is not used in any of these methods. Group VI and any of the set of II-V, VII and VIII are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Therefore, these inventions are patentably distinct.

The inventions of the set of II-V, VII and VIII are related in that each is directed to a different method of using the protein fragment of Group I, but these methods are not disclosed as being used together, and each one has different steps, a different function and a different effect. Therefore, these inventions are patentably distinct.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Further, this application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows.

a) in claim 6, Applicant must elect one of the therapeutic agents listed. This election will apply to claim 24.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in a) above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The following claim(s) are generic: 5 and 22.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-01-27

Rosanne Kosson

ROBERT A. WAX
PRIMARY EXAMINER